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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,055	09/24/2004	Hiroaki Sagawa	1422-0644PUS1	9947

2292 7590 06/09/2009

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/509,055	SAGAWA ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 5/22/09 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-3,5-7,10,12,28,29 and 31-35*.
   Claim(s) withdrawn from consideration: *8 and 14-27*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Amy E. Juedes/
Examiner, Art Unit 1644

Continuation of 11. does NOT place the application in condition for allowance because: The claims stand rejected under 35 U.S.C. 103 and for obviousness type double patenting for the reasons of record.

Applicant argues that Davis and Cardarelli et al. teach purified PBMC and not precursor cells, as recited in the instant claims. The instant claims specify that the precursor cells can be peripheral blood mononuclear cells. Both Davis and Cardarelli teach populations of peripheral blood mononuclear cells, and thus, said cells are "precursor" cells as recited in the instant claims.

Applicant further argues that the references do not teach a method wherein the expanded cytotoxic lymphocytes maintain cytotoxic activity longer than lymphocytes expanded in the absence of fibronectin. Davis et al. teach that the method results in increased number of CD8+ T cells (i.e. cytotoxic lymphocytes). Increasing the number of cytotoxic lymphocytes in a population of cells, as taught by Davis et al., would result in increased cytotoxic activity (i.e. "longer" cytotoxic activity). Furthermore, since the method of the cited references is the same as that of the instant claims, it would necessarily result in cytotoxic lymphocytes that maintain cytotoxic activity longer than those cultured in the absence of fibronectin.

Applicant further argues that the ordinary artisan would not have had a reasonable expectation of success in replacing the native fibronectin fragments taught by Davis and Cardarelli with the recombinant fibronectin fragment of the '423 patent. However, the '423 patent teaches that the recombinant fibronectin fragment is advantageous compared to native fibronectin, and that is is biologically active. Thus, the ordinary artisan would have had a reasonable expectation of success, since the '423 patent teaches that the recombinant fibronectin fragment in biologically active.

Applicant further argues that Cardarelli teaches away from the instant invention, since Cardarelli teaches an improved effect on cell proliferation with anti-CD3 and fibronectin in the absence of IL-2. Cardarelli teaches that IL-2 further enhances the proliferation of PBMC cultured with fibronectin and anti-CD3 (see Fig. 1). Thus, Cardarelli does not teach away from the use of IL-2, as asserted by Applicant, but rather provides motivation for including IL-2, since it further enhances proliferation in combination with fibronectin and anti-CD3.